



Cephalon, Inc. (“Cephalon”) respectfully submits this motion *in limine* to preclude Apotex Inc. (“Apotex”) from (1) introducing at trial certain late-produced documents relating to Apotex’s standard operating procedures (“SOPs”) for deriving samples from its active pharmaceutical product (“API”) batches, and (2) proffering expert testimony with regard to those SOPs.

### Background

[REDACTED]

[REDACTED] Particle size is a key issue in whether Apotex’s modafinil product described in its ANDA infringes the patent-in-suit.

As part of its very first set of discovery requests to Apotex, served shortly after entry of the Scheduling Order, in March of 2010, Cephalon requested all documents relating to Apotex’s testing of its proposed product. (*See* Ex. 2, Cephalon’s First Set of Requests for Production, Request Nos. 22, 30.) Even more specifically, Cephalon requested:

All documents relating to the particle size of Apotex’s Modafinil API, including any particle size measurements of Apotex’s Modafinil API conducted by Apotex or any other entity, including all documents relating to **any protocol(s) for particle size measurement used to measure the particle size distribution** of the Apotex Modafinil API.

(*Id.* at Request No. 40) (emphasis added).

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<sup>1</sup> Unless otherwise noted, all exhibits referenced herein are attached to the Declaration of Sadaf R. Abdullah In Support of Defendant Cephalon, Inc.’s Motion In Limine To Preclude Apotex Inc. From Relying On Late-Produced Documents Relating To Apotex’s Standard Operating Procedures.

Apotex produced no documents and no meaningful discovery on the procedures it used for sampling API to measure particle size of the modafinil of its proposed ANDA product.<sup>2</sup>

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Fact discovery closed on August 13, 2010. Yet Apotex waited until November 30, 2010 – *after* both opening and rebuttal expert reports had already been served, and a few days before reply expert reports were due – before producing a document entitled [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## Argument

### I. Legal Standard

When deciding whether evidence should be excluded due to a party's failure provide timely discovery, courts consider four factors: "(1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted; (2) the ability of the party to cure that

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<sup>2</sup> While Apotex produced a few sampling protocols during discovery, there was no indication or confirmation by witnesses that any of these was actually used in sampling the API for the test results provided in Apotex's ANDA.

prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or wilfulness in failing to comply with a court order or discovery obligation.” *Nicholas v. Pa. State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000) (affirming exclusion of plaintiff's expert witness because producing expert after the expert discovery deadline constituted a “flagrant disregard” of the court's pretrial order, and defendant would be prejudiced).

## **II. Apotex Should Be Precluded From Relying On The Late-Produced SOPs**

Each of the four factors weighs in favor of precluding Apotex from using late-produced SOPs at trial.

First, Cephalon was prejudiced and surprised by the late-produced SOPs. After conducting fact discovery without the SOPs, and after a demonstrated inability to obtain information and testimony regarding how the Apotex API samples were obtained, Cephalon was given these documents far too late to take meaningful discovery on them. Cephalon was unable to examine any witnesses regarding the SOPs.

This prejudice is not curable. In order to fully be able to respond to the late-produced protocols, Cephalon would need to re-open depositions of Apotex scientists, and perhaps depose new individuals from Apotex. It would also have to prepare additional expert opinion and testimony relating to the new documents. *See Astrazeneca AB v. Mutual Pharmaceutical Co., Inc.*, 278 F. Supp. 2d 491, 507 (E.D. Pa. 2003) (finding prejudice could not be cured where party would have “to re-open depositions and attempt to secure fact discovery (and expert opinions)”).

Allowing the evidence would disrupt the orderly and efficient trial. If Apotex were allowed to rely on the SOPs, Cephalon would be entitled to at least some additional discovery

and supplementation of its expert reports, and the extra time needed would disrupt the current schedule of the litigation (with trial on the patent issues set for March 29, 2010).

Finally, the facts support a finding that Apotex's late production was willful. Apotex provides no reason – nor can it – for the late production of the SOPs. These protocols, which have direct bearing on the reliability of test results of particle size distribution presented in Apotex's ANDA (*see, e.g.*, Antonietti Opening Rep. at ¶¶ 84-100) and therefore are highly relevant to issues of infringement, are Apotex documents, and appear to have been created and used by Apotex scientists at Apotex's manufacturing facilities. As such, they are documents within the custody, possession, and control of Apotex. Apotex was on notice that Cephalon was requesting these documents from the very first set of discovery requests served in this case, yet failed to produce them. Thus, the fourth factor of the standard also weighs in favor of exclusion of the SOPs. *See Haines v. Davies* 2009 WL 331433, at \*4 (M.D. Pa. Feb. 9, 2009) (finding willfulness where party failed to offer “substantial justification for the failure to satisfy” its obligations under the Federal Rules of Civil Procedure).

### **Conclusion**

For the foregoing reasons, Cephalon respectfully requests that the Court enter an order precluding Apotex from introducing into evidence the late-produced SOPs relating to its sampling of API for test data described in its ANDA, and from eliciting testimony at trial relating to the protocols.

Dated: March 7, 2011

Respectfully submitted,

/s/ Robert J. Gunther

Robert J. Gunther, Jr.  
WILMER CUTLER PICKERING  
HALE AND DORR LLP  
399 Park Avenue  
New York, NY 10022  
T: 212-230-8800  
F: 212-230-8888

Peter J. Kolovos  
Gregory P. Teran  
WILMER CUTLER PICKERING  
HALE AND DORR LLP  
60 State Street  
Boston, MA 02109  
T: 617-526-6000  
F: 617-526-5000

Nancy J. Gellman  
CONRAD O'BRIEN PC  
1515 Market Street, 16th Floor  
Philadelphia, PA 19102-1921  
T: 215-864-9600  
F: 215-864-9620

*Attorneys for Defendant Cephalon, Inc.*

**CERTIFICATE OF SERVICE**

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Motion *In Limine* To Preclude Apotex, Inc. From Relying On Late-Produced Documents Relating To Apotex's Standard Operating Procedures, Memorandum in Support (Redacted Version), Declaration of Sadaf R. Abdullah and Exhibits in Support (Filed Under Seal), and proposed Order were electronically filed pursuant to the Court's CM/ECF system, and that those documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

/s/ Robert J. Gunther, Jr.  
Robert J. Gunther, Jr.

Date: March 7, 2011